



TasP

Antiretroviral Treatment as Prevention - ANRS 12249
(Ukaphila Kwami, ukuphila kwethu (we health for our health))



00125375

Ukaphila kwami, ukuphila kwethu

Africa Centre TasP Trial

Serious Adverse Event Reporting

ANRS 12249 Initial SAE Notification

SAE-AI

Completed forms must be sent to
ANRS within 48 hrs.
Email: pharmacovigilance@anrs.fr
Fax: +33 153 946 002

SAE No.

SAE Visit Date

2014 09 11

Initial Notification Date

2014 09 15

Notification time

16 30

1. Patient details

TasP ID

4 2258

Name

N.N.N

Sex

☒ Male

☐ Female

Date of birth

1940 01 20

Enrolment date

2014 09 02

2. Measurements

Height

167 Cms

Last known: Weight

64.2

Kgs

Weight Date

2014 09 11

CD4 count

CD4 Date

Viral Load

Viral Load Date

3. By which criteria is this adverse event considered to be "Serious"?

Tick all that apply

☐ Resulted in death → Date of death

Probable cause

☐ Life threatening (i.e. at risk of death at time of event)

☒ Caused or prolonged hospitalisation (not elective hospitalisation for a pre-existing condition)

☐ Persistent or significant disability / incapacity

☐ Congenital abnormality / birth defect

☐ Grade 4 clinical and biological events

☐ Other serious, medically-important condition → Specify

4. Details of SAE

Enter each adverse event (e.g. symptom, sign, syndrome or diagnosis) on a separate line

Event Name

Date investigator
became aware

Date of onset of SAE

1. Renal failure grade 3 2014 09 15 2014 09 09

2. Hyperglycaemia grade 3 2014 09 15 2014 09 09

3.

4.

5.

5. Description of SAE

Include details of body site, relevant laboratory tests, treatments received and relevant medical history.

Attach copies of any relevant hospital records, laboratory test results etc.

This patient was asymptomatic when attending his baseline clinic TasP visit. He is known diabetic (type 2) and hypertensive. He transferred in already on ARV's. His baseline creatinine was 525 and urea 24.3. He was recalled to TasP clinic and reviewed by a doctor on 11/9/14. At clinic he was asymptomatic. Urine dip showed 3+ glucose. His fingerprick glucose was 22.8. He was referred directly to Hlabisa hospital for investigation.

DATA CAPT
2014-11-2
DCP-2

6. Medications

List all drugs taken (or prescribed) before occurrence of SAE

Generic Name	Daily dose	Route of administration	Indication	Date started	Date stopped	Causality assessment	Expected reaction? (BNF/SPC)	Action taken
1. Abacavir	800mg	PO	HIV			<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
2. Lamivudine	150mg	PO	HIV			<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
3. Efavirenz	600mg	PO	HIV			<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
4. Metformin	1g	PO	Diabetes			<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
5. Glibenclamide	5mg	PO	Diabetes			<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
6. Gliclazide	80mg	PO	Diabetes			<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop

7. Other causes of SAE, if unrelated to drugs mentioned in Section 6 above

7a. According to the physician, is this SAE likely to be related to participation in the research? Yes ☐ No ☒

7b. According to the physician, is this SAE related to any causes other than the research?
This includes the patient's medical history

Yes ☒ No ☐
Describe

Present at baseline with renal failure.
Post-discharge drugs will be rationalised.

8. SAE Outcome

Died

Unknown to date

☒ Ongoing

Improved

Recovered

→ A complementary SAE notification must be submitted within 8 days

→ Date of recovery

Recovered without sequelae

or

Recovered with sequelae

→ Describe

Physician reporting SAE

Name MELANIE HILL

Signature 

Date form completed 2014 09 15